

protects against contamination and deterioration. This includes:

(1) Holding the reserve samples under conditions consistent with product labels or, if no storage conditions are recommended on the label, under ordinary storage conditions; and

(2) Using the same container-closure system in which the packaged and labeled dietary supplement is distributed, or if distributing dietary supplements to be packaged and labeled, using a container-closure system that provides essentially the same characteristics to protect against contamination or deterioration as the one in which you distribute the dietary supplement for packaging and labeling elsewhere.

(b) You must retain reserve samples for 1 year past the shelf life date (if shelf life dating is used), or for 2 years from the date of distribution of the last batch of dietary supplements associated with the reserve samples, for use in appropriate investigations.

**§ 111.470 What requirements apply to distributing dietary supplements?**

You must distribute dietary supplements under conditions that will protect the dietary supplements against contamination and deterioration.

**§ 111.475 Under this subpart M, what records must you make and keep?**

(a) You must make and keep records required under this subpart M in accordance with subpart P of this part.

(b) You must make and keep the following records:

- (1) Written procedures for holding and distributing operations; and
- (2) Records of product distribution.

**Subpart N—Returned Dietary Supplements**

**§ 111.503 What are the requirements under this subpart N for written procedures?**

You must establish and follow written procedures to fulfill the requirements of this subpart.

**§ 111.510 What requirements apply when a returned dietary supplement is received?**

You must identify and quarantine returned dietary supplements until quality control personnel conduct a material review and make a disposition decision.

**§ 111.515 When must a returned dietary supplement be destroyed, or otherwise suitably disposed of?**

You must destroy, or otherwise suitably dispose of, any returned dietary supplement unless the outcome of a material review and disposition decision is that quality control personnel do the following:

(a) Approve the salvage of the returned dietary supplement for redistribution or

(b) Approve the returned dietary supplement for reprocessing.

**§ 111.520 When may a returned dietary supplement be salvaged?**

You may salvage a returned dietary supplement only if quality control personnel conduct a material review and make a disposition decision to allow the salvage.

**§ 111.525 What requirements apply to a returned dietary supplement that quality control personnel approve for reprocessing?**

(a) You must ensure that any returned dietary supplements that are reprocessed meet all product specifications established in accordance with § 111.70(e); and

(b) Quality control personnel must approve or reject the release for distribution of any returned dietary supplement that is reprocessed.

**§ 111.530 When must an investigation be conducted of your manufacturing processes and other batches?**

If the reason for a dietary supplement being returned implicates other batches, you must conduct an investigation of your manufacturing processes and each of those other batches to determine compliance with specifications.